

DETAILED ACTION

This application is a continuation of US patent application 09/777,616 which is a continuation of US patent application 09/360,056 which is a continuation of US patent application 08/833,948 which is a continuation-in-part of International patent application PCT/US95/14745 which is a continuation-in-part of US application 08/334,209.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2010, has been entered.

Receipt of Amendments/Remarks filed on February 1, 2010, is acknowledged. In response to Final office action dated July 30, 2009, applicant amended claims and added new claims. Claims 70-85, 87-96, & 98-105 are pending. Claims 70-85, 87-96, & 98-105 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

1. Receipt of a Supplemental Application Data Sheet is acknowledged. The Supplemental ADS correctly lays out the priority claim such that it agrees with the first line of the specification.

Inventorship

2. In view of the papers filed February 1, 2010, the inventorship in this nonprovisional application has been changed by the deletion of David Sackler.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Information Disclosure Statement

3. The information disclosure statement(s) (IDS) submitted on February 1, 2010, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement has been considered by the examiner.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the

reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 70-81, 87-92, & 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, 18-24, 26-32, 41-50, & 62-66 of U.S. Patent No. 5,958,452 (the '452 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '452 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '452 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '452 patent.

6. Claims 70-75, 77-85, 87, 88, 90-96, & 98-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 8-11, 15-21, 24-31, 33, 37, 39, 41, 46-53, & 57-66 of U.S. Patent No. 5,965,161 (the

'161 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '161 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making and using the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '161 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '161 patent. .

7. Claims 70-72, 75, 77-81, 87, 88, 90-92, & 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-25, & 27 of U.S. Patent No. 6,261,599 (the '599 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '599 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '599 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '599 patent.

8. Claims 70-72, 75, 77-81, 84, 85, 87, 88, 90-92, 95, 96, & 98-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-21, & 24-37 of U.S. Patent No. 6,335,033 (the '033 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other

because both the instant claims and the claims of the '033 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making and using the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '033 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '033 patent.

9. Claims 70-72, 75, 77, 78, 80, 81, 87, 88, 90, 92, & 98-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 7-17, 19, 22, 24-33, & 35-37 of U.S. Patent No. 6,706,281 (the '281 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '281 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making and using the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '281 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '281 patent.

10. Claims 70-72, 75, 77-85, 87, 88, 90-96, & 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-24, 27-29, & 32 of U.S. Patent No. 6,743,442 (the '442 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other

because both the instant claims and the claims of the '442 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '442 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '442 patent.

11. Claims 70-72, 75, 77, 78, 81, 100, & 101 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 15-21, 23-27, & 29 of U.S. Patent No. 7,510,727 (the '727 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '727 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers. The instantly claimed inventions are specific embodiments of the claimed invention of the '727 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '727 patent.

12. Claims 70-72, 75, 77, 78, 80, 81, 87, 88, 90, 92, & 100-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 35, 8-17, 19, 28, 31, & 33 of copending Application No. 12/372,460 (the '460 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the

claims of the '460 application are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '460 application and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '460 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Terminal Disclaimer

13. The terminal disclaimer filed by applicant on February 1, 2010, to remove the double patenting rejections does not comply with 37 CFR 1.321(b) and/or (c) because:

It does not include a recitation that any patent granted shall be enforceable only for and during such period that said patent is commonly owned with the application(s) or patent(s) which formed the basis for the double patenting rejection. See 37 CFR 1.321(c)(3).

The Office of Patent Legal Administration has determined that the language "legal title" is not equivalent to "common ownership" as required by 37 CFR 1.321(c)(3); therefore, the terminal disclaimer has not been approved and is insufficient to remove the double patenting rejections.

Conclusion

Claims 70-85, 87-96, & 98-105 are rejected. No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 8:00-4:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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